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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/590,531

08/24/2006

Rex J. Kuriger

47082-090USPX

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10/08/2008

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EXAMINER

EISEMAN, ADAM JARED

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

10/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/590,531 | Applicant(s) KURIGER ET AL. | |
| | Examiner ADAM J. EISEMAN | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/2/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Receipt of preliminary amendments filed on 2/1/2008 and 5/12/2008 are acknowledged and placed in the record on file. The amendments have been accepted and will be used for examination on the merits.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 3/2/2007 was received and placed in the record on file. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1-7 and 10-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dosmann (US Patent Application Publication US 2003/0171696) in view of Duchon et al (US Patent Application Publication US 2003/0018300).

Dosmann discloses an optical format for lancing the skin for collecting a body fluid sample from the lanced site comprising a hollow lancet (element 10) having a tip adapted to puncture skin and collect body fluid (paragraphs [0003]-[0004]; figures 1 and 2); the interior of the hollow lancet forming a channel (element 13) for moving a fluid sample from the tip to a reaction area (paragraph [0014]). The body fluid is drawn through the channel using capillary action or vacuum assisted capillary action (paragraph [0014]). Furthermore this optical format and integrated lance includes a viewing window to allow optical analysis of the sample by transmission spectrometry by passing a beam of light through the lance viewing windows to a detector (paragraphs [0004] and [0014]).

However, Dosmann does not disclose the integrated lancet used in combination with an apparatus with a body having an open end, a lancing mechanism disposed within the body coupled to the lancet opposite the tip and being adapted to move the lancet between a retracted position, a lancing position for puncturing the skin, and a collection position for collecting the body fluid; an outer end cap coupled to the open end of the body; or an inner end cap disposed within the outer end cap.

Duchon teaches a body fluid sampling device comprising a typical cocking and triggering mechanism used in integrated lancets that moves the lancet between

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retracted, lancing, and collecting positions (paragraphs [0064]-[0066]; figures 13e, 13g, and 13i), where the retracted and collecting positions are substantially the same.

Duchon further teaches outer (element 24) and inner (element 22) end caps which have an aperture for the lancet to pass (paragraphs [[0066]-[0067]; figure 13g). The outer cap has a first end coupled to the open end of the body (element 12) and the second end of the outer cap for contacting the skin (figure 13f). The second end of the inner cap also contacts the skin when the lancet is in the collecting position (figures 13h and 13i).

Regarding claims 1-7 and 10-34; it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Dosmann's optical format and integrated lancet for use as the lancet in the body fluid sampling device taught by Duchon. This would be obvious as applying the known technique of automated lancing mechanisms in body fluid collection, to the Dosmann's known optical format and integrated lancet to yield predictable results.

Further regarding claims 2, 3 and 10; Dosmann discloses the lancet defined by a square, fused silica capillary tube (paragraph [0010]).

Further regarding claim 4-6; Dosmann discloses the use of a vacuum around the lancing area to enhance blood flow (paragraph [0004]). It would have been obvious to one of ordinary skill in the art at the time of the invention that a vacuum used in the Dosmann/Duchon combination apparatus when the outer end cap is in contact with the skin would evacuate the air from the inner and outer ends caps and thusly create a

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vacuum that would position the skin of the test subject against the second end of the inner end cap.

Further regarding claims 5 and 6; it would have been obvious to one of ordinary skill in the art at the time of the invention to use known methods of applying a vacuum in blood collection devices including use of a diaphragm or bellows.

In regards to claim 7; Dosmann discloses using a light source for illuminating the reaction of the reagent and analyte in the fluid sample and a light detector for detecting light transmission through the reaction (paragraph [0014]).

Regarding claim 11; Duchon discloses that the retracted and collection positions are substantially the same (figures 13e and 13i).

Further regarding claims 12-34; the method as claimed is would define the obvious use of a Dosmann/Duchon combination in view of Dosmann's disclosure on the method of optically analyzing a body fluid collected from a puncture site (paragraph [0014]) and Duchon's disclosure of how the lancing body and mechanism works (paragraph [0066]-[0067]).

In regards to claim 18; it would have been obvious to one of ordinary skill of optical analysis to determine the start time of a colorimetric reaction based on the light transmitted through the lancet.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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US Patent 6,896,850 to Subramanian et al; discloses a micro sampling device having a window allowing a sample to be analyzed optically.

US Patent 4,627,445 to Garcia et al; discloses a glucose medical monitoring system.

US Patent 5,951,492 to Douglas et al; discloses a method and apparatus for sampling and analyzing a body fluid.

US Patent Application Publication US 2003/0018282 to Effenhauser et al; discloses a system for withdrawing small amounts of body fluid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM J. EISEMAN whose telephone number is (571)270-3818. The examiner can normally be reached on Mon-Thurs, 8:00 PM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AE

9/29/2008

/A. J. E./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736